REMARKS

The Office Action dated November 4, 2004 has been carefully reviewed. Claims 49-52, 55-61, and 124 are pending in this application. Applicants request reconsideration of this application in light of the remarks presented herein.

CLAIM REJECTIONS BASED ON §102

Claims 49-52, 55-61, and 124 were rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,165,220 issued to McKellop et al. (hereinafter "McKellop '220"). Applicants respectfully traverse this rejection.

The Examiner indicated in the 11/4/04 Office Action that claims 49-52, 55-61,and 124 are product-by-process claims. It is not clear from the text of the Office Action as to why the Examiner believes as such; however, based on the Examiner's reference to "gamma irradiated crosslinked layer of polymer" and "gamma irradiated polymer" it is assumed that the Examiner is asserting that these claim limitations render the claims product-by-process claims. Applicants respectfully disagree that such claim limitations are product-by-process limitations. In particular, the Examiner's unsupported, conclusory statement in the 11/4/04 Office Action (i.e., "Claims 49-52, 55-61, and new claim 124 are product-by-process claims.") does not satisfy the Patent Office's (i.e., the Examiner's) initial burden for establishing that claims are product-by-process claims. Such an unsupported, conclusory statement is not a legally sufficient substitute for a reasoned application of the relevant legal standard. To the contrary, the limitations "gamma irradiated crosslinked layer of polymer" and "gamma irradiated polymer" refer to the type of material used in the claimed bearing, not any particular method for making such material. In other words, a "gamma irradiated polymer" no more connotes a particular process than would a claimed "quench hardened steel" or a "pressure treated wood" – it merely refers to the type of material (in this case, polymer) used in the claimed article.

Even if, for arguments sake, the "gamma irradiated crosslinked layer of polymer" and "gamma irradiated polymer" limitations could be construed as a product-by-

process limitations, the Examiner has not established how McKellop '220 anticipates claims 49-52, 55-61, and 124. In particular, in order to be a proper anticipation rejection, it must be established that no structural differences exist between the claimed product (including the purported process limitation) and the prior art. In the case of claims 49-52, 55-61, and 124, the Examiner has not established how the claimed bearing including the "gamma irradiated" polymer is structurally the same as (i.e., not structurally distinct from) the E-beam irradiated or chemically treated bearings of McKellop '220. The initial burden is on the Examiner to establish a proper rejection under § 102, and in the case of the purported process limitations of claims 49-52, 55-61, and 124, the Examiner has not done so. Simply asserting that Applicants' claims are product-by-process claims does not obviate the Examiner's initial burden of establishing a proper rejection under § 102, and, as a result, the burden of responding has not shifted to Applicants.

Not only has the Examiner not established a proper rejection under § 102, Applicants argue that no such rejection exists. In particular, even if, for arguments sake, the "gamma irradiated crosslinked layer of polymer" and "gamma irradiated polymer" limitations could be construed as a product-by-process limitations, and even if, for arguments sake, the Examiner had attempted to meet his initial burden of formulating an initial rejection under § 102, the use of gamma irradiated polyethylene creates structural differences relative to the E-beam crosslinked polyethylene and chemically crosslinked polyethylene used in McKellop '220 thereby rendering the invention of claims 49-52, 55-61, and 124 patentably distinct over McKellop '220. To support this, Applicants have submitted the following three articles in an IDS filed concurrently herewith:

> (1) F-W Shen & H McKellop Surface-gradient crosslinked polyethylene acetabular cups, Clinical Orthopaedics and Related Research, # 430, P 80 – 88. (hereinafter "Reference (1)")
>
> (2) H McKellop, F-W Shen, et al Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements Journal of Orthopaedic Research 17:157-167. (hereinafter "Reference (2)")

(3) L Martinotto, et al Space charge behavior of chemically cross-linked and radiation cross-linked polyethylene Proceedings of 2000 Conference on Electrical Insulation and Dielectric Phenomena. (hereinafter "Reference (3)")

*Note that both Reference (1) and Reference (2) are authored by Harry McKellop and Fu-Wen Shen, the named inventors of the primary patent reference being relied upon in the 11/4/04 Office Action (i.e., McKellop '220, U.S. Patent No. 6,165,220).

As can be seen from a careful reading of Reference (1), unlike gamma radiation, E-beam has limited penetration through the polymer (e.g., polyethylene) thereby resulting in a gradient of crosslinking. The profile and depth of the gradient is related to the source strength. E-beam crosslinked UHMWPE shows a characteristic gel content curve of: (1) initial rise in gel content from outer surface to subsurface, (2) a plateau section of maximal gel content, followed by (3) a decreasing gradient of gel content, and (4) a non-crosslinked PE section with zero gel content if the polymer is thick enough (see Reference (1), Figure 2).

As to the magnitude of gel content, McKellop et al reported that 50-kGy (5.0 Mrad) E-beam crosslinked UHMWPE (the surface crosslinked material) has a maximal gel content of around 93% (see, e.g., Reference (1), Figure 2), while 45-kGy Gamma crosslinked UHMWPE has a gel content of 97.8% (see, Reference (2), Table 8) (note, 1 Mrad = 10kGy). In other words, polyethylene exposed to lesser dosage of gamma irradiation (i.e., 4.5 Mrad) is crosslinked to a greater degree than polyethylene exposed to a greater dosage of E-beam radiation (i.e., 5.0 Mrad). McKellop et al further report that as the dosage of gamma radiation increases, the crosslink density likewise increases (see, e.g., Reference (2), page 164, first full paragraph). As such, it is expected that the above-identified difference in gel content between E-beam and gamma irradiated polyethylene (i.e., 93% vs. 97.8%) would be even greater had the respective specimens been subjected to equal dosages of radiation. To wit, Applicants internal testing has shown that a 50-kGY (5.0 Mrad) gamma-treated UHMWPE bar has a gel content in the range of 98% - 99% throughout its thickness. As such, even though polyethylene crosslinked by the use of different methods can be characterized by a number of structural similarities (e.g., crystallinity), these data

demonstrate that a structural difference relating to crosslink densities does in fact exist between gamma irradiated polyethylene and E-beam irradiated polyethylene.

Chemical crosslinking of polyethylene starts with heat activation of organic peroxide. Free radicals so generated abstract hydrogen atoms from methylene segments in the polymer chain, thereby creating carbon-based free radicals. The combination of two carbon-based free radicals produces a crosslink in the polyethylene.

Martinotto et al (Reference (3)) reported that crosslinking byproducts can affect, in a negative way, the aging of XLPE cable insulation under thermo-electrical stress. Removal of the byproducts is not always feasible. The byproducts of peroxide crosslinking process are various organic species depending on the starting organic peroxide. For example, Luperox 130 (2,5-dimethyl-2,5-di-(tert-butylperoxy)-3-hexyne), generates tert-butyl alcohol and 2,5-dimethyl-2,5-hydroxyl-3-hexyne residues after its decomposition and extraction of hydrogen atoms from polyethylene. Some of these byproducts are volatile and may diffuse out of polymer. Nevertheless, a majority of the byproducts in peroxide-crosslinked UHMWPE are trapped in the polymer matrix due to limited diffusivity in highly viscous molten UHMWPE mass.

Another aspect of peroxide-crosslinked UHMWPE is the residual peroxide left after curing/molding. The non-reacted peroxide has potential to decompose/degrade as time passes and consequently induces oxidative degradation in polymer. For example, the half life of Luperox 130 is 9 minutes 21 seconds at 170° C, and the minimum curing time at 170° C is as long as 1 hour 33 minutes (the minimum curing time from half life calculator was provided by the specialchem4polymers.com website). It is not uncommon to observe temperature gradient in a mold during molding/curing. Peroxide-crosslinked UHMWPE often requires prolonged annealing to reduce, and possibly eliminate, the last traces of un-reacted peroxide (see, e.g., Reference (2)). Chemically crosslinked UHMWPE, if not thoroughly annealed, may have unexpected degradation tendency.

As such, even though polyethylene crosslinked by the use of different methods can be characterized by a number of structural similarities (e.g., crystallinity), the above-

description demonstrates that a structural difference relating to chemical composition does in fact exist between peroxide-crosslinked UHMWPE and gamma-crosslinked UHMWPE. Such a different chemical composition is characterized by, amongst other things, the presence of decomposition byproducts and potentially un-reacted peroxide residues.

Wear rate may be used to demonstrate additional structural differences between polymers crosslinked by the different techniques of interest (i.e., chemical, E-beam, and gamma). For example, the following table was compiled from the work of McKellop et al, as reported in References (1) and (2). It is a comparison of the wear rate of E-beam crosslinked UHMWPE, chemical crosslinked UHMWPE, and gamma crosslinked UHMWPE. It is interesting to note that the same wear test machine and input conditions were used by McKellop et al for each material. The data related to E-beam crosslinked UHMWPE and chemical crosslinked UHMWPE may be found in Reference (1), Table 2, whereas the data related to gamma crosslinked UHMWPE may be found in Reference (2), Table 2.

Material	Wear Rate (mm^3 per million cycles)
5.0 Mrad E-beam (surface) Crosslinked UHMWPE	25.6 +/- 2.5
1.0 % Peroixde Crosslinked UHMWPE	17.1 +/- 2.0
4.5 Mrad Gamma Crosslinked UHMWPE	9.3 +/- 0.9

The wear rate data clearly show that the gamma crosslinked polyethylene has a greater degree of polymer network formation than either of the E-beam crosslinked polyethylene or the chemical crosslinked polyethylene. As such, even though polyethylene crosslinked by the use of different methods can be characterized by a number of structural similarities (e.g., crystallinity), these data demonstrate the existence of at least some structural differences in the materials.

Other structural differences also exist between the claimed composite bearings of Applicants' claims 49-52, 55-61, and 124 and the bearings disclosed in McKellop '220. In

particular, the bearing comprising molded layers of UHMWPE of claims 49-52, 55-61, and 124 defines a structure of stepwise transition from one degree of crosslinking to another or from one type (i.e., crosslinked and non-crosslinked) of UHMWPE to the other. On the other hand, the E-beam treated and chemically treated UHMWPE bearings of McKellop '220 define a gradual gradient in the crosslinking profile. (See also Reference (1) where McKellop et al describe the treatment of bearings in a similar manner as in McKellop '220. As described on page 83, first two paragraphs under "RESULTS" and shown in FIG. 2, such a gradient is formed as a result of E-beam treatment. Similarly, as described on page 85, first six lines and shown in FIG. 7, a gradient is also formed as a result of chemical treatment.)

In light of the above discussion, Applicants submit that McKellop '220 does not anticipate claim 49. Claim 49 includes the limitation of "a *gamma irradiated* crosslinked layer of polymer." A structure or feature corresponding to such a limitation is not found in McKellop '220. Moreover, claim 49 also includes the recitation of "a non-crosslinked layer of polymer *molded* to said [gamma irradiated] crosslinked layer of polymer." Again, a structure or feature corresponding to such a limitation is not found in McKellop '220. In the 11/4/04 Office Action, the Examiner indicated that "it is clearly stated and shown that the non-crosslinked layer and the crosslinked layer are molded to form the bearing" in column 9, lines 58-63 of McKellop '220. This citation was provided by the Examiner in response to Applicants' statement in their response to the first office action where the Applicants pointed out that McKellop '220 does not disclose "a non-crosslinked layer of polymer molded to ***said*** crosslinked layer of polymer." Applicants respectfully point out that the "said crosslinked layer of polymer" limitation quoted from claim 49 is merely a shorthand reference to "a gamma irradiated crosslinked layer of polymer" as defined in the previous line of claim 49. Applicants have reviewed the passage of McKellop '220 cited by the Examiner (i.e., column 9, lines 58-63) and can find no mention of a non-crosslinked layer of polymer molded to a gamma irradiated crosslinked layer of polymer, nor has such a feature been found anywhere else in McKellop '220. The only mention of molding relates to the molding of PE powder mixed with peroxide. Respectfully, Applicants maintain their previous assertion that the

limitation of "a non-crosslinked layer of polymer molded to said [gamma irradiated] crosslinked layer of polymer" is not disclosed in McKellop '220.

Claims 50-52 and 55 depend from claim 49 and are not anticipated by McKellop '220 for at least the reasons discussed in regard to claim 49.

Claim 56 is not anticipated by McKellop '220 for reasons similar to as discussed above in regard to claim 49. For example, claim 56 includes the limitations of "a first layer of *gamma irradiated* polymer..." and "a second layer of polymer *molded* to said first layer of [gamma irradiated] polymer...". As discussed above in regard to claim 49, structures or features corresponding to such limitations are not found in McKellop '220.

Claims 57-61 and 124, depend from claim 56 and are not anticipated by McKellop '220 for at least the reasons discussed in regard to claim 56.

CLAIM REJECTIONS BASED ON §103

Claims 49-52, 55-61, and 124 were rejected under 35 U.S.C. §103(a) as being obvious over McKellop '220 in view of U.S. Patent No. 6,652,943 issued to Tukachinsky (hereinafter "Tukachinsky"). Applicants respectfully traverse this rejection.

In the 11/4/04 Office Action, the Examiner indicates that McKellop '220 "discloses crosslinking of a polymer layer utilizing radiation such as an electron beam", and asserts that "Tuckachinsky teaches the equivalence of gamma rays and electron beams in order to achieve polymer crosslinking." The Examiner further indicates that "it would still have been prima facie obvious...to have utilized a gamma irradiated crosslinked layer of polymer in the McKellop bearing" since "Tuckachinsky teaches that gamma irradiation is a recognized technique for polymer crosslinking." Apparently, in an attempt to arrive at the invention of Applicants' claim 49, the Examiner is modifying the method of McKellop '220 to use gamma irradiation in lieu of E-beam irradiation to crosslink the outer layer of the bearing. It is a fundamental tenet of patent law that a prima facie case of obviousness cannot be established in the absence of some teaching, motivation, or suggestion supporting the modification or combination of the references relied upon in making the rejection. The rule

of law for a finding of obviousness under 35 U.S.C. § 103(a) was reiterated recently by the Court of Appeals for the Federal Circuit as follows, "[w]hen patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness." In re Lee, 277 F.3d 1338 at 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002); See also McGinley v. Franklin Sports, Inc., 262 F.3d 1339 at 1351-52, 60 USPQ2d 1001 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors). The Federal Circuit expounded upon the necessity of finding some teaching or motivation to combine the references in the references themselves concluding that "[t]he factual inquiry whether to combine references must be thorough and searching." In re Lee, 61 U.S.P.Q.2d at 1433 (Fed. Cir. 2002). The teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

In an apparent attempt to establish a case of obviousness in the present case, the Examiner stated that "Tuckachinsky teaches that gamma irradiation is a recognized technique for polymer crosslinking." While this statement is indeed technically accurate (i.e., it is true that gamma irradiation can be used to crosslink a polymer), this statement in no way forms a legally sufficient teaching, motivation, or suggestion to combine McKellop '220 and Tuckachinsky in the very specific manner proposed by the Examiner. Indeed, the regurgitation of a well known scientific principal is not *ipso facto* a legally sufficient

substitution for the required factual analysis clarified and confirmed in *Lee*. It is the Examiner's burden to point to such motivation, and the Examiner has not done so.

Furthermore, not only has the Examiner not offered a legally sufficient teaching, motivation, or suggestion to combine McKellop '220 and Tuckachinsky, it is believed that no such motivation exists. For example, McKellop '220 teaches away from the proposed combination with Tuckachinsky. Indeed, to use gamma irradiation to crosslink the polymer of McKellop '220 would destroy the two-layered bearing of McKellop '220. Gamma irradiation is deep penetrating. If substituted for the E-beam of McKellop '220, the entire thickness of the bearing would be crosslinked thereby destroying the desired surface gradient crosslinking. In other words, there would not be a layer of non-crosslinked or nearly non-crosslinked layer in the interior of the bearing as desired by McKellop '220. This is supported by the work of McKellop et al as reported in Reference (1) where it is stated "[b]ecause of the high penetration power of gamma radiation, the resultant cross-linking nearly is constant ***through the entire thickness of the PE component.***" See Reference (1), page 80, right-hand column, lines 14-17, emphasis added. In short, one skilled in the art desiring to make the gradual surface-gradient crosslinked bearings of McKellop '220 would not use gamma irradiation as taught by Tuckachinsky since doing so would *not* produce the desired gradient, but rather would crosslink the bearing throughout its entire thickness.

As a result, the Examiner has not established a prima facie case of obviousness with regard to Applicants' claim 49.

Claims 50-52 and 55 depend from claim 49 and are not obvious over the combination of McKellop '220 and Tuckachinsky for at least the reasons discussed in regard to claim 49.

Claim 56 is not obvious over the combination of McKellop '220 and Tuckachinsky for reasons similar to as discussed above in regard to claim 49. For example, claim 56 includes the limitation of "a first layer of *gamma irradiated* polymer...". As discussed above in regard to claim 49, use of such structures or features is not obvious over the combination of McKellop '220 and Tuckachinsky.

Claims 57-61 and 124, depend from claim 56 and are not obvious over the combination of McKellop '220 and Tuckachinsky for at least the reasons discussed in regard to claim 56.

CONCLUSION

In view of the foregoing remarks, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,
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